DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PRODUCT LICENSE APPLICATION FOR CRYOPRECIPITATED ANTIHEMOPHILIC FACTOR

Form Approved: OMB No. 0910-0124.
Expiration Date: November 31, 2001.
See Page 2 For OMB Statement.

DATE SUBMITTED

NOTE: This report is mandated by Section 351 of the Public Health Service Act, the Federal Food, Drug and Cosmetic Act, Section 502, and Title 21 CFR Part 600. No license may be granted unless this completed application form has been received.

1. MANUFACTURER'S NAME, ADDRESS, AND ZIP CODE

TELEPHONE NO. *(Include area code)*

2. ESTABLISHMENT NAME, ADDRESS, AND ZIP CODE *(If different from Item 1)*

TELEPHONE NO. *(Include area code)*

3. TYPE OF APPLICATION *(Check one)* ☐ ORIGINAL ☐ AMENDED

4. THIS REQUEST FOR LICENSING INCLUDES CRYOPRECIPITATED ANTIHEMOPILIC FACTOR PREPARED BY:

☐ a. WHOLE BLOOD COLLECTION - CRYO. IS PREPARED IN ACCORDANCE WITH CURRENT FEDERAL REGULATIONS AND MY WHOLE BLOOD APPLICATION SUBMITTED WITH THIS APPLICATION; OR PREVIOUSLY FILED _____.

☐ b. PLASMAPHERESIS - CRYO. IS PREPARED IN ACCORDANCE WITH CURRENT FEDERAL REGULATIONS AND MY SOURCE PLASMA LICENSE APPLICATION SUBMITTED WITH THIS APPLICATION; OR PREVIOUSLY FILED _____.

☐ c. AUTOMATED OR SEMI - AUTOMATED PROCEDURES - CRYO. IS PREPARED IN ACCORDANCE WITH CURRENT FEDERAL REGULATIONS AND THE COPY OF OPERATING PROCEDURES SUBMITTED. SUBMIT FORM FDA 3098e ALSO.

5. QUALITY CONTROL TESTS	YES	NO
a. ARE PERFORMED ON PREMISES?		
b. IF "NO" TO "a" ABOVE, LIST NAME AND ADDRESS OF ESTABLISHMENT WHERE PERFORMED.		
c. A WRITTEN AGREEMENT IS ON FILE PERMITTING AUTHORIZED INSPECTORS TO INSPECT TESTING LABORATORY.		
d. RESULTS OF TESTS ARE RECEIVED BY YOUR ESTABLISHMENT WITHIN 10 DAYS?		

CERTIFICATION

I certify that there is documentation in the records which supports that, for each unit of the products covered in this application, all critical manufacturing steps have been performed in accordance with current Federal Regulations, and that the responsible individual has signed the pertinent manufacturing records on the day of manufacture.

I also certify that all statements made in this application are true and complete to the best of my knowledge and ability. I am familiar with the pertinent Sections of Part 600 - 640 of Title 21, Code of Federal Regulations, and am aware of my responsibilities described therein.

WARNING: A willfully false certification is a criminal offense. U.S. Code, Title 18, Section 1001.

TYPED NAME OF RESPONSIBLE HEAD	SIGNATURE OF RESPONSIBLE HEAD	DATE

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ATTACHMENTS

A. Samples of complete labeling *(including all overlays and circular * with directions for use)* for all products checked in Item 4.

   Labels should be submitted on Form FDA 2567, "Trasmittal Labels and Circulars", in triplicate and may be either mock-ups or printers' proofs.

B. "Product License Application for the Manufacture of Source Plasma (Human)", Form FDA 2600 (Item 5b), if applicable.

C. Automated procedures and Form FDA 3098e, "The Manufacturre of Products Prepared by Cytapheresis", (Item 5c), if applicable.

D. Copies of quality control tests for previous 2 months.

* If AABB / ARC circular is used without modification, submit one copy only.

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